

## NOTICES OF EXEMPT RULEMAKING

The Administrative Procedure Act requires the *Register* publication of the rules adopted by the state's agencies under an exemption from all or part of the Administrative Procedure Act. Some of these rules are exempted by A.R.S. §§ 41-1005 or 41-1057; other rules are exempted by other statutes; rules of the Corporation Commission are exempt from Attorney General review pursuant to a court decision as determined by the Corporation Commission.

### NOTICE OF EXEMPT RULEMAKING

#### TITLE 9. HEALTH SERVICES

#### CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM ADMINISTRATION

*Editor's Note: The following Notice of Exempt Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 2033.) The Governor's Office authorized the notice to proceed through the rulemaking process on August 9, 2011.*

[R12-143]

#### PREAMBLE

- 1. Article, Part, or Section Affected (as applicable) Rulemaking Action**  
R9-22-710 Amend
- 2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific), and the statute or session law authorizing the exemption:**  
Authorizing statute: A.R.S. §§ 36-2903.01, 36-2907  
Implementing statute: A.R.S. § 36-2904  
Statute or session law authorizing the exemption: Laws 2011, Ch. 31, § 34
- 3. The effective date of the rule and the agency's reason it selected the effective date:**  
August 1, 2012
- 4. A list of all notices published in the Register as specified in R1-1-409(A) that pertain to the record of the exempt rulemaking:**  
Notice of Proposed Exempt Rulemaking: 18 A.A.R. 1429, June 29, 2012
- 5. The agency's contact person who can answer questions about the rulemaking:**  
The close of the comment period was July 9, 2012.  
Name: Mariaelena Ugarte  
Address: AHCCCS  
Office of Administrative and Legal Services  
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Phoenix, AZ 85034  
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- 6. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered to include an explanation about the rulemaking:**  
The Veterans Health Care Act of 1992 established the 340B program in section 340B of the Public Health Service Act (PHS Act). The 340B program requires drug manufacturers participating in Medicaid to provide discounted covered outpatient drugs to certain eligible health care entities, known as covered entities. Covered entities include disproportionate share hospitals, family planning clinics, and federally qualified health centers, among others as described under 42 U.S.C. 256b(a)(4). As of October 2010, approximately 15,000 covered-entity locations were enrolled in the 340B program.  
The Health Resources and Services Administration (HRSA) administers the 340B program. In 2000, HRSA issued guidance directing covered entities to refer to State Medicaid agencies' policies for applicable billing policies in

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regards to 340B claims. The Centers for Medicare and Medicaid Services (CMS), which administers the Medicaid program, does not require State Medicaid agencies to set 340B policies. The AHCCCS Administration recently promulgated a rule which describes the reimbursement methodology applicable to FQHCs and FQHC Look Alikes and their contacted pharmacies for drugs that are subject to 340B pricing. This rule became effective February 1, 2012. In response to questions regarding the scope of this rule, the AHCCCS Administration found that further clarification was needed to define an FQHC and FQHC Look-Alike pharmacy. Additionally, the proposed rule clarifies that contracted pharmacies shall not submit claims for drugs dispensed under an agreement with a 340B entity as part of the 340B drug pricing program.

Arizona Laws 2011, Ch. 31, § 34, authorized the agency to adopt rules necessary to implement a program within available appropriations, including making changes to reimbursement rates and methodologies, and to make changes to rules relating to cost sharing responsibilities of eligible persons.

Arizona Laws 2011, Ch. 31, § 34 exempts the Administration from the formal rulemaking requirements of A.R.S. Title 41, Chapter 6.

Arizona Law 2011, Ch. 31, § 34, which authorizes this exempt rulemaking, requires public notice with an opportunity for public comment of at least 30 days. Public notice of this rulemaking will be accomplished through publication of this rulemaking on the agency web site on May 31, 2012. A supplemental notice will also appear in the *Arizona Administrative Register* in advance of the close of the comment period. In addition, notice will be directed to those individuals who, prior to this proposed rulemaking have notified the agency of their desire to receive such notices directly pursuant to A.R.S. § 36-2903.01(B)(6).

**7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:**

The Department of Health and Human Services Office of Inspector General issued a report with the following recommendations: (1) inform states that they should incorporate 340B policies into their Medicaid State Plans, (2) inform states of alternative methods of identifying 340B claims that we identified in this report, and (3) facilitate communication between HRSA and states by providing a list of State Medicaid pharmacy directors to HRSA and instructing states to contact HRSA when errors in the Medicaid Exclusion File are found. CMS and HRSA concurred with the recommendations.

The study “Cost of Dispensing Study: An independent comparative analysis of U.S. prescription dispensing costs by Grant Thornton LLP” demonstrated a national median cost of dispensing.

Arizona used an adjustment factor using geographic practice cost indices resulting in the AZ cost of dispensing. The Administration has analyzed the data through the study and AHCCCS claims data at the NDC level for the 1st quarter of 2011; the results of the analysis demonstrated a net savings valued at approximately \$7.1M annually.

**8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:**

Not applicable

**9. The summary of the economic, small business, and consumer impact, if applicable:**

The AHCCCS Administration believes that the amendment to this rule defining an FQHC and FQHC Look-Alike pharmacy will provide clarity to those providers that are unsure of their participation in the 340B program and therefore include appropriate reimbursement for claims paid at the 340B pricing. Although no economic impact is associated with the revision proposed in this rulemaking, the estimated savings to the state associated with the prior rulemaking effective February 2012 is approximately \$7.1M. It should be noted that these approximate savings and dispensing fee costs do not take into consideration the prescriptions filled at 340B contracted pharmacies which are not subject to this methodology.

**10. A description of any changes between the proposed rulemaking, including any supplemental proposed rulemaking, and the final rulemaking package (if applicable):**

No substantive changes were made between the proposed rule and the final rule.

**11. An agency’s summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments, if applicable:**

No comments were received by the end of the comment period July 9, 2012.

**12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules. When applicable, matters shall include, but not be limited to:**

**a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:**

Not applicable

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**b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than the federal law and if so, citation to the statutory authority to exceed the requirements of federal law:**

Not applicable

**c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:**

No analysis was submitted.

**13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:**

None

**14. Whether the rule was previously made, amended, repealed or renumbered as an emergency rule. If so, the agency shall state where the text changed between the emergency and the exempt rulemaking packages:**

Not applicable

**15. The full text of the rules follows:**

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM  
ADMINISTRATION

ARTICLE 7. STANDARDS FOR PAYMENTS

Section

R9-22-710. Payments for Non-hospital Services

ARTICLE 7. STANDARDS FOR PAYMENTS

**R9-22-710. Payments for Non-hospital Services**

**A.** Capped fee-for-service. The Administration shall provide notice of changes in methods and standards for setting payment rates for services in accordance with 42 CFR 447.205, December 19, 1983, incorporated by reference and on file with the Administration and available from the U.S. Government Printing Office, Mail Stop: IDCC, 732 N. Capitol Street, NW, Washington, DC, 20401. This incorporation by reference contains no future editions or amendments.

1. Non-contracted services. In the absence of a contract that specifies otherwise, a contractor shall reimburse a provider or noncontracting provider for non-hospital services according to the Administration's capped-fee-for-service schedule.
2. Procedure codes. The Administration shall maintain a current copy of the National Standard Code Sets mandated under 45 CFR 160 (October 1, 2004) and 45 CFR 162 (October 1, 2004), incorporated by reference and on file with the Administration and available from the U.S. Government Printing Office, Mail Stop: IDCC, 732 N. Capitol Street, NW, Washington, DC, 20401. This incorporation by reference contains no future editions or amendments.
  - a. A person shall submit an electronic claim consistent with 45 CFR 160 (October 1, 2004) and 45 CFR 162 (October 1, 2004).
  - b. A person shall submit a paper claim using the National Standard Code Sets as described under 45 CFR 160 (October 1, 2004) and 45 CFR 162 (October 1, 2004).
  - c. The Administration may deny a claim for failure to comply with subsection (A)(2)(a) or (b).
3. Fee schedule. The Administration shall pay providers, including noncontracting providers, at the lesser of billed charges or the capped fee-for-service rates specified in subsections (A)(3)(a) through ~~(A)(3)(d)~~ (d) unless a different fee is specified in a contract between the Administration and the provider, or is otherwise required by law.
  - a. Physician services. Fee schedules for payment for physician services are on file at the central office of the Administration for reference use during customary business hours.
  - b. Dental services. Fee schedules for payment for dental services are on file at the central office of the Administration for reference use during customary business hours.
  - c. Transportation services. Fee schedules for payment for transportation services are on file at the central office of the Administration for reference use during customary business hours.
  - d. Medical supplies and durable medical equipment (DME). Fee schedules for payment for medical supplies and DME are on file at the central office of the Administration for reference use during customary business hours. The Administration shall reimburse a provider once for purchase of DME during any two-year period, unless the Administration determines that DME replacement within that period is medically necessary for the member. Unless prior authorized by the Administration, no more than one repair and adjustment of DME shall be reimbursed during any two-year period.

**B.** Pharmacy services. The Administration shall not reimburse pharmacy services unless the services are provided by a phar-

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macy having a subcontract with a Pharmacy Benefit Manager (PBM) contracted with AHCCCS. Except as specified in subsection (C), the Administration shall reimburse pharmacy services according to the terms of the contract.

C. FQHC Pharmacy reimbursement.

1. For purposes of this Section the following terms are defined:
  - a. "340B Drug Pricing Program" means the discount drug purchasing program described in 42 U.S.C. 256b.
  - b. "340B Ceiling Price" means the maximum price that drug manufacturers can charge covered entities participating in the 340B Drug Pricing Program as reported by the drug manufacturer to HRSA.
  - c. "340B entity" means a covered entity, eligible to participate in the 340B Drug Pricing Program, as defined by the Health Resources and Human Services Administration.
  - d. "Actual Acquisition Cost (AAC)" means the purchase price of a drug paid by a pharmacy net of discounts, rebates, chargebacks and other adjustments to the price of the drug. The AAC excludes dispensing fees.
  - e. "Contracted Pharmacy" means an arrangement through which a 340B entity may contract with an outside pharmacy to provide comprehensive pharmacy services utilizing medications subject to 340B pricing.
  - f. "Dispensing Fee" means the amount paid for the professional services provided by the pharmacist for dispensing a prescription. The Dispensing Fee does not include any payment for the drugs being dispensed.
  - g. "Federally Qualified Health Center" means a public or private non-profit health care organization that has been identified by HRSA and certified by CMS as meeting the criteria under ~~Sections~~ sections 1861(aa)(4) and 1905(l)(2)(B) of the Social Security Act and receives funds under ~~Section~~ section 330 of the Public Health Service Act.
  - h. "Federally Qualified Health Center Look-Alike" means a public or private non-profit health care organization that has been identified by HRSA and certified by CMS as meeting the definition of "health center" under ~~Section~~ section 330 of the Public Health Service Act, but does not receive grant funding under ~~Section~~ section 330.
  - i. "FOHC or FQHC Look-Alike pharmacy" means a pharmacy that dispenses drugs to FOHC or FQHC-LA patients and that is owned and/or operated by an FOHC/FQHC-LA or by an entity that reports the costs of an FOHC/FQHC-LA on its Medicare Cost Report, whether or not collocated with an FOHC or an FQHC Look-Alike.
2. Effective the later of February 1, 2012, or CMS approval of a State Plan Amendment, an FQHC or FQHC Look-Alike shall:
  - a. Notify the AHCCCS provider registration unit of its status as a 340B covered entity no later than:
    - i. 30 days after the effective date of this Section;
    - ii. 30 days after registration with the Health Resources and Services Administration (HRSA) for participation in the 340B program; or
    - iii. The time of application to become an AHCCCS provider.
  - b. Provide the 340B pricing file to the AHCCCS Administration upon request. The 340B pricing file shall be provided in the file format as defined by AHCCCS.
  - c. Identify 340B drug claims submitted to the AHCCCS FFS PBM or the Managed Care Contractors' PBMs for reimbursement. The 340B drug claim identification and claims processing for a drug claim submission shall be consistent with claim instructions issued and required by AHCCCS to identify such claims.
3. The FQHC and the FQHC Look-Alike pharmacies shall submit claims for AHCCCS members for drugs that are identified in the 340B pricing file, whether or not purchased under the 340B pricing file, with the lesser of:
  - a. The actual acquisition cost, or
  - b. The 340B ceiling price.
4. The AHCCCS Fee-for-Service and Managed Care Contractors' PBMs shall reimburse claims for drugs which are identified in the 340B pricing file dispensed by FQHC and FQHC Look-Alike pharmacies, whether or not purchased under the 340B pricing file, at the amount submitted under subsection ~~(3)~~ (C)(3) plus a dispensing fee listed in the AHCCCS Capped Fee-For-Service Schedule unless a contract between the 340B entity and a Managed Care Contractor's PBM specifies a different dispensing fee.
5. Contracted pharmacies shall not submit claims for drugs dispensed under an agreement with the 340B entity as part of the 340B drug pricing program, and the The AHCCCS Administration and Managed Care Contractors shall not reimburse such claims ~~contracted pharmacies for drugs dispensed under an agreement with the 340B entity as part of the 340B drug pricing program.~~
6. The AHCCCS Administration and Managed Care Contractors shall reimburse contracted pharmacies for drugs not dispensed under an agreement with the 340B entity as part of the 340B program at the price and dispensing fee set forth in the contract between the contracted pharmacy and the AHCCCS or its Managed Care Contractors' PBMs. Neither the Administration nor its Managed Care Contractors will reimburse a contracted pharmacy that does not have a contract with the Administration or MCO's PBM.
7. The AHCCCS Administration and its Managed Care Contractors shall reimburse FQHC and FQHC Look-Alike pharmacies for drugs that are not eligible under the 340B Drug Pricing Program at the price and dispensing fee set forth in



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Although the AHCCCS Administration will begin processing new applications on and after June 25, 2012, because eligibility for KidsCare is prospective, eligibility based on new applications will not be sooner than August 1, 2012.

Pursuant to Arizona Laws 2011, 1st Special Session, Ch. 1 (Senate Bill 1001), § 2, this proposed rule is exempt from the requirements for formal rulemaking otherwise required by A.R.S. Title 41, Chapter 6.

7. **A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:**  
None
8. **A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:**  
Not applicable
9. **The summary of the economic, small business, and consumer impact, if applicable:**  
Not applicable
10. **A description of any changes between the proposed rulemaking, including any supplemental proposed rulemaking, and the final rulemaking package (if applicable):**  
No substantive changes have been made between the proposed rulemaking and the final rulemaking package.
11. **An agency's summary of the public or stakeholder comments made about the rulemaking and the agency response to the comments, if applicable:**  
No comments were received as of the close of the comment period, July 21, 2012, 5:00 p.m.
12. **Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules. When applicable, matters shall include, but not be limited to:**  
None
  - a. **Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:**  
Not applicable
  - b. **Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than the federal law and if so, citation to the statutory authority to exceed the requirements of federal law:**  
Not applicable
  - c. **Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:**  
Not applicable
13. **A list of any incorporated by reference material and its location in the rule:**  
None
14. **Whether the rule was previously made, amended, repealed or renumbered as an emergency rule. If so, the agency shall state where the text changed between the emergency and the exempt rulemaking packages:**  
Not applicable
15. **The full text of the rules follows:**

TITLE 9. HEALTH SERVICES

CHAPTER 31. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM  
CHILDREN'S HEALTH INSURANCE PROGRAM

ARTICLE 4. KIDSCARE II PROGRAM

Section  
R9-31-401. KidsCare II Program

ARTICLE 4. KIDSCARE II PROGRAM

**R9-31-401. KidsCare II Program**

- A. Subject to CMS approval and the availability of funding under the special terms and conditions of the 1115 Waiver, the Administration shall establish the KidsCare II program.
- B. Subject to the availability of funding, the following children are potentially eligible under this Section notwithstanding the closure of new enrollment under Article 3 on December 21, 2009, due to a lack of available funding:
  1. Children with household income at or below 175% of FPL, who are discontinued for eligibility under 9 A.A.C. 22,

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- Article 14 effective on or after May 1, 2012, due to age.
2. Children with household income at or below 175% of FPL, whose application for assistance was denied or discontinued as ineligible under 9 A.A.C. 22 on or after December 21, 2009 but who were determined potentially eligible for KidsCare as of the date of that denial or discontinuance and whose eligibility for KidsCare was not determined because the Administration stopped processing applications due to insufficient funding pursuant to R9-31-301(C).
  3. Children not described in subsection (B)(2) with household income at or below 175% of FPL.
- C. Beginning on or before May 1, 2012, the Administration shall send notice of potential eligibility under this Section to as many households with children described in subsection (B)(2) as is estimated by the Administration as likely to result in the return of a sufficient number of applications to increase enrollment under this Section to the extent of available funding under this Section.
- D. Notice of potential eligibility:
1. Children who were placed on the waiting list established under R9-31-302(F) on an earlier date shall receive notice before children placed on the waiting list on a later date.
  2. Notwithstanding subsection (D)(1), all children in the household will receive notice and be determined for eligibility based on the child in the household with the earliest applicable date.
  3. Households shall have 30 days to return an application to the Department.
  4. If notices that are initially sent under subsection (C) do not result in sufficient applications to enroll as many children as allowed by available funding, the Administration shall send out additional notices as described in subsection (C).
  5. ~~Once the Administration has enrolled the maximum number of children consistent with funding made available under this Section, the Administration shall stop processing applications and determining eligibility under this Section.~~
- E. The Department shall review all applications for a determination of eligibility under 9 A.A.C. 22. If the Department determines that a child is not eligible under 9 A.A.C. 22 but has income at or below 175% of FPL and meets all other eligibility criteria under R9-31-303, the Department shall refer the application to the Administration.
- F. The Administration shall accept the Department's determinations regarding eligibility criteria without requiring the household to submit a new application under this Section or to re-verify information verified by the Department.
- G. Upon referral of an application from the Department, the Administration shall:
1. Determine whether the application referred by the Department was from a household with a child described in subsection (B)(1) or from a household that received a notice under subsection (D) that submitted an application to the Department within 30 days of the Administration's request for a new application;
  2. Process applications for children described in subsection (B)(3) beginning June 25, 2012;
  - 2-3. Determine whether the household has any unpaid premiums as described in R9-31-1420 and, if so, the Administration shall require the household to pay the past due premium within 20 days from notification as a condition of determining a child eligible under this Section; ~~and~~
  - 3-4. Enroll children under this Section based on the date that the Administration determines the child eligible; ~~and~~
  5. Stop processing applications and determining eligibility under this Section once the Administration has enrolled the maximum number of children consistent with funding made available under this Section.
- H. Effective date of initial enrollment.
1. For an eligibility determination completed by the 25th day of the month, enrollment shall begin on the first day of the month following the determination of eligibility.
  2. For an eligibility determination completed after the 25th day of the month, enrollment shall begin on the first day of the second month following the determination of eligibility.
- I. Any child who is not determined eligible under subsection (G) shall remain on the waiting list described in R9-31-302(F).
- J. Eligibility for children under this Section ends on December 31, 2013.
- K. Except as otherwise provided by this Section, eligibility shall be determined in accordance with the provisions of this Chapter.